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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Arne H. DEGGERDAL et al. Art Unit : 1623
Serial No. : 08/849,686 Examiner : H. Owens, Jr.
Filed : August 21, 1997
Title : ISOLATION OF NUCLEIC ACID

Commissioner for Patents
Washington, D.C. 20231

RESPONSE

In response to the Examiner's action dated January 6, 2000, please consider the remarks set forth below.

Pending Claims

Claims 1-24 are pending in the application. Applicants acknowledge the allowability of claims 22-24.

The Invention

The application discloses methods for isolating nucleic acids from a sample. The methods use a solid support that includes an organic polymer, and the nucleic acid is bound to the support in the presence of a detergent and in the absence of any chaotropic agent.

35 U.S.C. §102

The Examiner maintains the rejection of claims 1, 2, and 14 as anticipated by the 1994 Pharmacia Biotechnology Products catalog. This rejection is respectfully traversed.

The rejection is premised on the belief that the catalog:

discloses oligo(dT) Cellulose ... for the isolating of mRNA from a cell lysate which can certainly contain any conventional detergent. Oligo(dT) Cellulose is certainly an organic support which can bind

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mRNA in the presence of detergents. Furthermore, the material can be washed and the nucleic acid eluted with heat which simply denatures the double-stranded nucleic acid. One of skill in the art would clearly recognize [that clearly recognize] the common use of detergents within the art of purification of nucleic acids; moreover, that the Pharmacia product could be used in the absence of a chaotropic agent, barring evidence to the contrary, which has not been presented by applicant. [Emphasis added]

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The Examiner has misconstrued the standard for anticipation. Applicants respectfully remind the Examiner that the standard for anticipation requires that the reference teach every aspect of the claimed invention, either (a) expressly or (b) inherently:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference [See MPEP 2131, quoting *Verdegaal Bros v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)] Emphasis added

First, the Examiner must agree that the Pharmacia Biotechnology Products catalog does not expressly teach at least two of the characteristics required by the present claims, i.e., that the product be used in (i) the presence of a detergent and (ii) the absence of a chaotropic agent. Since the cited reference is silent on these two elements, it certainly cannot be said to expressly teach them.

Neither does the Pharmacia Biotechnology Products catalog inherently describe the claimed invention. A rejection based on principles of inherent anticipation requires that the claimed matter be necessarily disclosed in the prior art:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. **Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference**, and that it would be so recognized by persons of ordinary skill. [See, M.P.E.P. 2131.02, quoting *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991). Emphasis added.]

At least two characteristics required by the present claims, i.e., (i) the presence of a detergent and (ii) the absence of a chaotropic agent, are not necessarily present in the composition disclosed in the 1994 Pharmacia Biotechnology Products catalog. The mere

assertion in the Office Action that the "cell lysate can certainly contain any conventional detergent" and "that the Pharmacia product could be used in the absence of a chaotropic agent" do not render these limitations necessarily present in the composition disclosed in the cited reference.

The standard for anticipation is not reliant on whether Applicants can provide evidence to contradict the Examiner's reasoning that one skilled in the art could have used a detergent, or whether one skilled in the art might not have used a chaotropic agent with the Pharmacia product. For a claim to be anticipated, the cited reference must explicitly or inherently disclose the present invention. There is nothing on the record establishing that the limitations of (i) the presence of a detergent and (ii) the absence of a chaotropic agent are explicitly or inherently disclosed in the cited reference. The rejection under 35 U.S.C. §102 should be withdrawn.

35 U.S.C. §103

The Examiner has maintained the rejection of claims 1-12 and 14-18 as obvious over the 1994 Pharmacia Biotechnology Products catalog.

Applicants respectfully point out again to the Examiner that a rejection for obviousness requires that the prior art teach or suggest all of the claim limitations. MPEP 2142. In the present case, the rejection for obviousness is flawed because the cited catalog fails to disclose or suggest that the claimed method could or should be carried out (i) in the presence of a detergent and (ii) in the absence of a chaotropic agent. The Examiner makes reference to the fact that there is "no evidence that one of skill in the art could not use the claimed Pharmacia invention in the absence of chaotropic agents." Establishing that a reference "can" be modified as claimed is not sufficient to establish prima facie obviousness. As explained in the MPEP:

the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. [MPEP 2143.01.]

The cited reference does not suggest the desirability of using the Pharmacia product (i) in the presence of a detergent and (ii) in the absence of a chaotropic agent, and the Examiner has pointed to no disclosure that does so suggest.

The Examiner makes reference to the fact that when determining obviousness, the level of ordinary skill in the pertinent art must be taken into account. While true, that point does nothing to establish the Examiner's case. The Examiner "must ascertain what would have been obvious at the time the invention was made" MPEP 2141.03. The cited reference contains no teaching or suggestion to use the Pharmacia product (i) in the presence of a detergent and (ii) in the absence of a chaotropic agent. Without some teaching or suggestion to provide the requisite motivation, those skilled in the art, regardless of their "level of skill", would not have found it obvious to modify the teachings of the Pharmacia catalog. This is a case of hindsight reconstruction based on Applicant's disclosure, which of course is not permitted.

The Examiner also states:

Applicant's claim that the targeting of the Pharmacia product is limited to mRNA tails is countered by the inclusion of "fractionization of oligonucleotides" apart from mRNA isolation set forth in the Pharmacia catalog clearly indicating that nucleic acids are within the scope of the invention....

Applicants acknowledge that the Examiner is correct in noting that the Pharmacia product can also be used "for fractionation of oligonucleotides". However, the present invention is clearly distinct from the disclosure of the 1994 Pharmacia Catalog. In the Pharmacia method, the cellulose resin linked to oligo(dT) or oligo(dA) is used to recognize and bind target sequences having specific predefined sequences, e.g., mRNA with poly(A) tails or oligonucleotides that have a sequence complementary to dT or dA. The Pharmacia method requires sequence-specific binding: i.e., binding to oligo(dT) or oligo(dA). In contrast, in the present invention, binding is sequence-independent, and nucleic acid molecules bind non-specifically to the solid support (see page 5, lines 21-22, of the specification). The Pharmacia method therefore does not overcome the problems recited in the present application, i.e., the need for improved methods of isolation that are quick and simple and that do not require washing steps (see page 5, lines 5-7, and page 11, line 36, through page 12, line 2, of the specification). The Pharmacia method is not concerned with, nor suggestive of, the claimed method in which sequence-independent binding occurs. Indeed, hybridization techniques, such as the Pharmacia technique, are routinely preceded by a blocking step to block available sites on the solid support

specifically to avoid sequence-independent binding. Thus, the present invention is concerned with a new approach for isolating nucleic acid molecules which would not have been obvious in view of the cited art. Because the cited reference fails to disclose or suggest modifying the Pharmacia sequence-dependent method by including detergent and avoiding use of a chaotropic agent, in order to arrive at the presently claimed method (which can function in a sequence-independent manner), the rejection for obviousness should be withdrawn.

35 U.S.C. §112(2)

The indefiniteness rejection of claims 13 and 19-21 was maintained in the Office Action. It is unclear to applicants why the rejection is maintained. In the May 12, 1999, Office Action the Examiner stated "applicant is requested to clarify for the record precisely what is the scope of claims 13 and 19-21". Applicants responded by explaining that the surface charge properties of the hydrophobic surfaces, polyurethane, polystyrene and latex are non-ionic. However, in the present Office Action the Examiner seems to be requesting that the claims be amended. Applicants believe that the metes and bounds of the claims are clear and are unsure of what concerns the Examiner. Clarification is requested.

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CONCLUSION

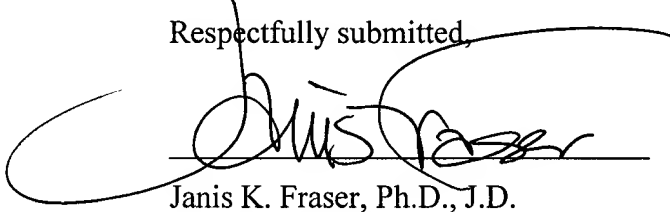
Applicants submit that all of the claims are now in condition for allowance, which action is requested.

Enclosed is a petition for automatic extension, along with the required fee. Please charge any additional fees, or make any credits, to Deposit Account No. 06-1050, reference no. 08269/003001.

Respectfully submitted,

Date:

July 5, 2000


Janis K. Fraser, Ph.D., J.D.
Reg. No. 34,819

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906